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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/994,495	Applicant(s) SOMACK ET AL.	
	Examiner William H. Beisner	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 and 51-57 is/are pending in the application.
- 4a) Of the above claim(s) 20-47 and 51-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 48, 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-19 and 48-50 in Paper No. 7 is acknowledged.
2. Claims 20-47 and 51-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Franciskovich et al.(US 5,603,899).

With respect to claim 1, the reference of Franciskovich et al. discloses a system (10) for processing a plurality of fluid samples that includes a plurality of sample purification devices (12). Each device (12) comprising a tubular body (50) having a first end (62), a first end opening (70), a second end (54), a second end opening (52) and a species-immobilizing filter (51,53) held within the tubular body (50). The system includes removable caps (58) for sealing the second

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end opening (52) and a sealing device (16) having a surface (36) adapted to individually seal each of the first end openings (70). The sealing device is a tray (16) comprising a plurality of recesses (34). Note the tray seals the first end openings during processing of the fluid samples. The tray is sealed to plate (14) holding the devices (12) during centrifugation (See column 4, line 60, to column 5, line 20). Vacuum port (80) and gasket (15) are not required and/or used during the centrifugal processing (See column 5, line 59, to column 6, line 4).

With respect to claims 2 and 19, the surface (36) of the sealing device (16) has a plurality of recesses (34) therein.

With respect to claims 3-5, the reference also discloses the use of caps (64,68) adapted to seal the first end opening (70).

With respect to claim 16, the device would be an assembly.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
8. Claims 1-9 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franciskovich et al.(US 5,603,899) in view of Sanadi (US 5,342,581).

The reference of Franciskovich et al. discloses a system for processing a plurality of fluid samples that includes a plurality of biological sample purification devices (12). Each device (12) comprising a tubular body (50) having a first end (54), a first end opening (52), a second end (62), a second end opening (70) and a species-immobilizing filter (51,53) held within the tubular body (50). The system includes removable caps (64,68) for sealing the second end opening (70).

With respect to claim 1, while the reference discloses the use of caps (58) for individually sealing each of the first end opening (52), the reference fails to disclose the use of a sealing device having a surface adapted to individually seal each of the first end openings wherein the sealing device is a tray with a plurality of recesses.

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The reference of Sanadi discloses a variety of well-known means for sealing the openings of an array of openings of an array of tubes (See column 1, lines 34-64). Figure 4A of Sanadi discloses a sealing device or tray (61) with recesses (71) that can be use from the number of possible sealing structures.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a sealing device as suggested by the reference of Sanadi for the known and expected result of providing means recognized in the art for sealing an array of openings. Use of the device of Sanadi would be advantageous because it would eliminate the need for an individual cap for each opening while providing the sealing suggested by the primary reference of Franciskovich et al. (See column 1, lines 34-64, of Sanadi).

With respect to claims 2 and 19, the sealing tray (61) includes recesses (71).

With respect to claims 3-5, the reference of Franciskovich et al. discloses that the first end openings can be sealed with caps (58) and the second end openings sealed with caps (64,68).

With respect to claims 6 and 7, the filter is located at the second end (62) of the device.

With respect to claims 8 and 9, the reference of Sanadi discloses that the use of a sealing tape is a well known alternative to the use of caps or the use of the device of Figure 1 or 4A of the reference of Sanadi (See column 1, lines 34-64).

With respect to claim 16, when using the sealing device as suggested by the reference of Sanadi, the structure would be in the form of an assembly.

With respect to claim 17, the reference of Franciskovich et al. discloses the use of a sealing device (16) having a surface (36) adapted to seal the second end openings (70).

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With respect to claim 18, the sealing device (16) of the reference of Franciskovich et al. includes recesses (34) for receiving the second end openings (70).

9. Claims 10, 11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franciskovich et al.(US 5,603,899) in view of Bankier et al.(US 5,846,493).

The reference of Franciskovich et al. has been discussed above.

With respect to claims 10 and 11, while the reference of Franciskovich et al. employs a species-immobilizing filter (51,53), the reference does not disclose that the filter is disclosed as a nucleic acid purification filter that can bind nucleic acids.

The reference of Bankier et al. discloses that it is known in the art to provide an array of separation columns (1) that are similar to that of the primary reference of Franciskovich et al. with a nucleic acid purification filter (38) that can bind nucleic acids.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a separation filter as disclosed by the reference of Bankier et al. in the device of the primary reference for the known and expected result of separating nucleic acids from biological samples while providing the advantages of the column system disclosed by the primary reference of Franciskovich et al.

With respect to claims 13-15, while the device of the modified reference as discussed above is employed for the purification of DNA fragments from a sample, the reference is silent as to the source of the sample. However, cell lysates, whole blood and tissue extracts are all known in the art to be sources of nucleic acid samples. As a result, it would have been obvious

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to one of ordinary skill in the art to employ any well-known source of nucleic acid based merely on the intended sample to be analyzed.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Franciskovich et al.(US 5,603,899) in view of Bankier et al.(US 5,846,493) taken further in view of Leying et al.(US 5,955,271) and Sheer et al.(US 5,124,041).

The combination of the references of Franciskovich et al. and Bankier et al. has been discussed above.

The above claim differs by reciting that the system includes a polymerase solution in the purification device.

The reference of Leying et al. discloses that it is well known in the art to purify and amplify nucleic acid in the same vessel (See Example 1).

The reference of Sheer et al. discloses that it is known in the art to perform PCR in situ on the purification media of a device (See column 8, lines 46-47).

In view of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the system with PCR reagents for the known and expected result of performing PCR on the purified sample in the filter device. As shown in the prior art, in situ PCR is an acceptable alternative to elution of the purified nucleic acid that is amplified in a separate vessel.

11. Claims 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fernwood et al.(US 5,151,719) in view of Sanadi (US 5,741,463).

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The reference of Fernwood et al. discloses a plate (11,16) having a first surface and a second surface that opposes the first surface and a plurality of through-holes (12, 41) where each through-hole extend from the first surface to the second surface and define a first opening at the first surface and a second opening at the second surface (See Figure 4). The plate includes a plurality of species-immobilizing filters (13) disposed in each through-hole. The reference discloses that the filter can be a continuous sheet or individual disks (See column 3, lines 12-30). Note a membrane sheet or disk (13) clamped between members (11 and 16) result in a plate device (11,16) with a filter (13) immobilized within the through holes (12,41) of the device.

Claim 48 differs by reciting that the system includes a first sealing device adapted to individually seal each of the first openings and a second sealing device adapted to seal each second end opening wherein the sealing device is a tray including a plurality of recesses. Dependent claim 49 specifies that the first sealing device is a plurality of caps.

The reference of Sanadi discloses that when using an array of tube or multi-well plates (with or without a filtration feature) contamination of the samples within the individual wells or tubes is a problem (See column 1, lines 34-44). The reference also discloses a number of devices known in the art for sealing the openings associated with arrays of tubes or wells. The devices include plates, tapes and caps (See column 1, lines 44-64). Figure 4A discloses a sealing device or tray (61) that includes a plurality of recesses formed by elements (73).

In view of this teaching, it would have been well within the purview of one having ordinary skill in the art to employ any of the sealing devices discussed by the reference of Sandi to seal the openings of an array device, such as that of the primary reference of Fernwood et al.,

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with a sealing tray of Figure 4A or individual caps for the known and expected result of preventing contamination of the wells of the array device.

12. Claims 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGraw et al. in view of Sanadi (US 5,741,463).

The reference of McGraw et al. discloses a plate (8) having a first surface and a second surface that opposes the first surface and a plurality of through-holes (11) where each through-hole extend from the first surface to the second surface and define a first opening at the first surface and a second opening at the second surface (See Figure 1B and Figure 1C). The plate includes a plurality of species-immobilizing filters (7) disposed in each through-hole.

Claim 48 differs by reciting that the system includes a first sealing device adapted to individually seal each of the first openings and a second sealing device adapted to seal each second end opening wherein the sealing device is a tray including a plurality of recesses.

Dependent claim 49 specifies that the first sealing device is a plurality of caps.

The reference of Sanadi discloses that when using an array of tube or multi-well plates (with or without a filtration feature) contamination of the samples within the individual wells or tubes is a problem (See column 1, lines 34-44). The reference also discloses a number of devices known in the art for sealing the openings associated with arrays of tubes or wells. The devices include plates, tapes and caps (See column 1, lines 44-64). Figure 4A discloses a sealing device or tray (61) that includes a plurality of recesses formed by elements (73).

In view of this teaching, it would have been well within the purview of one having ordinary skill in the art to employ any of the sealing devices discussed by the reference of Sandi

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to seal the openings of an array device, such as that of the primary reference of Fernwood et al., with a sealing tray of Figure 4A or individual caps for the known and expected result of preventing contamination of the wells of the array device.

Response to Arguments

13. Applicant's arguments filed 11/23/2004 have been fully considered but they are not persuasive.

With respect to the rejection of claims 1-5, 16 and 19 over the reference of Franciskovich et al. under 35 USC 102, during the interview of Nov. 5, 2004 it was argued that the sealing device (16) of the reference of Franciskovich et al. did not individually seal each opening in view of vacuum port (80). Applicants' representative reasoned that if each opening was sealed, a vacuum would not be capable of being provided to each of the openings as required by the reference of Franciskovich et al. The Examiner was persuaded by these comments. However, the reference of Franciskovich et al. also discloses an embodiment wherein a centrifuge is employed rather than vacuum. Gasket (15) is not required to communicate port (80) with the openings and in the absence of gasket (15) the openings are sealed by the plate (16) as is required of the instant claims (See column 4, line 60, to column 5, line 20; and column 5, line 59, to column 6, line 4).

Applicants' amendments and associated comments, filed 11/23/04, pages 17-18, are persuasive to overcome the rejection of claim 48 over the reference of Chen et al. under 35 USC 102.

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Applicants' amendments and associated comments, filed 11/23/04, pages 18-19, are persuasive to overcome the rejection of claims 1, 3-9 and 16-18 over the combination of the references of Franciskovich et al. and Nix et al..

With respect to the combination of the references of Franciskovich et al. and Sanadi, Applicants arguments, filed 11/23/04, pages 19-20, state that the combination does not teach or suggest the claimed invention because neither of the references of Franciskovich et al. nor Sanadi discloses or suggests a sealing device having a surface adapted to individually seal each of the first end openings of a plurality of devices during the processing of the fluid samples and wherein the sealing device is a tray with a plurality of recesses.

In response, the reference of Franciskovich et al. clearly disclose sealing the first end openings during processing of the fluid samples (See column 5, lines 1-5). The combination of the references suggests replacing the caps of the reference of Franciskovich et al. with a sealing device as suggested by Figure 4A of Sanadi. The device of Figure 4A of Sanadi discloses a sealing tray (61) with recesses (73). The resulting combination as suggested by the prior art clearly meets the instant claim limitations.

With respect to the combination of the references of Franciskovich et al. and Bankier et al., Applicants argue, page 20, 11/23/04, that the teachings of Bankier et al. do not make up for the deficiencies previously argues with respect to the reference of Franciskovich et al.

In response, the reference of Bankier et al. was relied upon as a tertiary reference to address the additional claim limitations of dependent claims 10, 11, and 13-15. For reasons already of record, the Examiner is of the position that the reference of Franciskovich et al. meets the sealing device limitations previously argued by Applicants.

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With respect to the combination of the references of Franciskovich et al. and Bankier et al. taken further in view of Leying et al. and Sheer et al., Applicants argue, page 20-21, 11/23/04, that the further teachings of Leying et al. and Sheer et al. do not make up for the deficiencies previously argues with respect to the reference of Franciskovich et al.

In response, the references of Leying et al. and Sheer et al. were merely relied upon as tertiary references to address the additional claim limitations of dependent claim 12. For reasons already of record, the Examiner is of the position that the reference of Franciskovich et al. meets the sealing device limitations previously argued by Applicants.

With respect to the combination of the references of Fernwood et al. and Sanadi, Applicants arguments, filed 11/23/04, page 21, state that the combination does not teach or suggest the claimed invention because neither of the references of Fernwood et al. nor Sanadi discloses or suggests a sealing device having a surface adapted to individually seal each of the first end openings of a plurality of devices during the manipulation of the fluid samples and wherein the sealing device is a tray with a plurality of recesses.

In response the intended use of the sealing device, statements of intended use carry no patentable weight in apparatus type claims. The combination meets the structural limitations of the instant claim even if the sealing device may be used to merely seal the device prior to use rather than during use. The combination of the references suggests the employment of a sealing device as suggested by Figure 4A of Sanadi. so as to protect the interior of the filter device. The device of Figure 4A of Sanadi discloses a sealing tray (61) with recesses (73). The resulting combination as suggested by the prior art clearly meets the instant claim limitations.

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With respect to the combination of the references of McGraw et al. and Sanadi, Applicants arguments, filed 11/23/04, pages 21-22, state that the combination does not teach or suggest the claimed invention because neither of the references of McGraw et al. nor Sanadi discloses or suggests a sealing device having a surface adapted to individually seal each of the first end openings of a plurality of devices during the manipulation of the fluid samples and wherein the sealing device is a tray with a plurality of recesses.

In response the intended use of the sealing device, statements of intended use carry no patentable weight in apparatus type claims. The combination meets the structural limitations of the instant claim even if the sealing device may be used to merely seal the device prior to use rather than during use. The combination of the references suggests the employment of a sealing device as suggested by Figure 4A of Sanadi. so as to protect the interior of the filter device. The device of Figure 4A of Sanadi discloses a sealing tray (61) with recesses (73). The resulting combination as suggested by the prior art clearly meets the instant claim limitations.

For the reasons discussed above, the claims remain rejected over the prior art of record.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William H. Beisner
Primary Examiner
Art Unit 1744

WHB